

<b>In re: PHARMACEUTICAL INDUSTRY</b>	)	<b>MDL No. 1456</b>
<b>AVERAGE WHOLESAL PRICE LITIGATION</b>	)	<b>Master File No. 01-12257-PBS</b>
	)	<b>Subcategory Case No. 06-11337</b>
	)	
	)	<b>Hon. Patti B. Saris</b>
<b>THIS DOCUMENT RELATES TO:</b>	)	
	)	
<i>State of California ex rel. Ven-A-Care of the Florida</i>	)	
<i>Keys, Inc. v. Abbott Labs, Inc. et al.,</i>	)	
Civil Action No. 03-11226-PBS	)	
	)	

## PRELIMINARY STATEMENT

In its opposition to Dey’s Individual Motion for Partial Summary Judgment, California does not dispute, and thereby concedes, basic facts fatal to its opposition to Dey’s Motion for Partial Summary Judgment. *First*, in 1999, Dey began sending letters to the Medi-Cal program expressly stating that its AWP’s did not reflect prices paid or charged in the marketplace, and were set at the launch of a drug and not subsequently changed. *Second*, in contrast to Dey’s AWP’s, the WAC’s that Dey reported, which are Dey’s invoice prices to its wholesalers, declined over time such that, by January 1999, “spreads” of at least 99 percent between the AWP and WAC for each of the Subject Drugs would have been readily apparent to anyone who compared the two. *Third*, publicly available reports prepared by the Office of Inspector General for the United States Health and Human Services Department (the “HHS-OIG”) in the late 1990s that would have been reviewed by Medi-Cal personnel documented

significant differences between compendia AWP and providers' actual costs for many of the Subject Drugs.

Neither the letters directly sent to the Medi-Cal program nor the many HHS-OIG Reports prompted California to contact Dey to discuss its price reporting practices. Instead, California ignored the letters and the reports and continued to rely on the compendia AWP to reimburse providers for Dey's drugs. In light of this evidence, the notion that Dey could have knowingly caused the submission of false claims after January 1999 is untenable.

In response to this overwhelming evidence, California twists the law and contends that, in order for its knowledge to bar Dey's claims, it must have expressly approved of Dey's practice. This is not the law. Rather, the question is whether, in light of its knowledge of an alleged falsity, the government nonetheless acquiesces in the practice at issue. The evidence is clear that, by 1999, California had acquiesced and its claims after that time should be dismissed.

Finally, California does not dispute that there is no evidence in the record at all that the AWP for Dey's atenolol, piroxicam, alprazolam, hydrocodone, theophylline, EpiPen, EpiPen Jr., DuoNeb, sodium chloride solution or sterile water products (collectively, the "Conceded Drugs") were false or that California has suffered any damages as a result of reimbursement claims paid on these drugs. Accordingly, claims for these drugs should be dismissed in their entirety.

## **ARGUMENT**

### **I. CALIFORNIA MISSTATES THE LAW APPLICABLE TO "GOVERNMENT KNOWLEDGE"**

California's opposition to Dey's individual motion for partial summary judgment rests on the false premise that government knowledge of the alleged false claim only bars a California False Claims Act (the "CFCA") claim when it is accompanied by some sort of express

approval of the claim. As discussed at length in Defendants' Joint Brief in Opposition to Plaintiffs' Motion for Partial Summary Judgment, there is no requirement of "express approval." The relevant question is whether California acquiesced in the payment of claims that exceeded providers' actual acquisition costs. *See United States ex rel. Englund v. Los Angeles County*, No. CIV. S-04-282 LKK/JFM, 2006 WL 3097941, at \*12 (E.D. Cal. Oct. 31, 2006) (granting summary judgment for defendants because "the Federal government knew what [defendant] was doing and *implicitly* approved of [defendant's] actions") (emphasis added); *see also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n.8 (5th Cir. 2003) (en banc) (Jones, J. concurring) (noting that "[t]he government's knowledge *and acquiescence* in its contractor's actions" is "highly relevant" to negate scienter, and "is also bound up with whether the claim itself was false.") (emphasis added).

California has failed to cite any authority to support its contention that government knowledge must be coupled with express government approval. None of the cases California cites for this principle hold that there must be some direct communication of approval between the government and the defendant. *See People v. Duz-Mor Diagnostic Lab., Inc.*, 68 Cal. App. 4th 654, 672 (Cal. Ct. App. 1998); *Laraway v. Sutro & Co.*, 96 Cal. App. 4th 266, 272 (Cal. Ct. App. 2002); *Am. Contract Servs. v. Allied Mold & Die, Inc.*, 94 Cal. App. 4th 854, 865 (Cal. Ct. App. 2001). Rather, the relevant question is the depth of the government's knowledge and the degree to which it nevertheless permits the claim. *See United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 954 (10th Cir. 2008) ("[W]e conclude that neither the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference. Instead, the focus

properly rests upon the depth of the government’s knowledge of the facts underlying the allegedly false claim and the degree to which the government invites that claim.”)

**II. CALIFORNIA’S ARGUMENTS CONCERNING THE PARTICULAR EVIDENCE OF GOVERNMENT KNOWLEDGE CITED BY DEY ARE MERITLESS**

**A. Price Notification Letters**

California does not dispute that, beginning in 1999, Dey sent letters to the Medi-Cal program and other state Medicaid agencies expressly noting that: (a) Dey’s AWP was not a price that was actually charged or paid for Dey’s drugs; (b) that it was Dey’s general practice to set its AWP before it began selling the drug and not to subsequently change it; and (c) that Dey understood that this practice was consistent with industry practice.<sup>1</sup> (Dey SOF at ¶¶ 28-31, 35.)<sup>2</sup> Nor does California dispute that it never attempted to contact Dey concerning these statements or otherwise investigate the claims made in them. (Dey SOF at ¶¶ 32-34, 36.)

Rather, California argues that these letters never revealed the actual differences between the compendia AWP for Dey’s drugs and the actual acquisition costs, and therefore California could never have knowingly acquiesced in Dey’s conduct. However, there is no authority to support that the level of government knowledge requires the degree of specificity California contends is necessary. In *Massachusetts v. Mylan Laboratories*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008), the MDL Court held that a government knowledge defense was viable

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<sup>1</sup> California contends that Dey did not always follow the practice of setting its AWP at launch and not subsequently changing them, and points to instances where Dey did change its AWP after launch. (See Plaintiff’s Brief in Opposition to Dey’s Motion for Partial Summary Judgment (Dkt. No. 6779) (“Cal. Dey Opp. Brief”) at 4.) This fact is irrelevant and immaterial, as most of the drugs for which California contends Dey raised its AWP are no longer at issue. Dey has only adjusted an AWP for one of the five drugs that remains at issue once, in 2000, when it lowered the AWP for its acetylcysteine. (See Declaration of Sarah L. Reid in Support of Dey, L.P., and Dey, Inc.’s Motion for Partial Summary Judgment, (Dkt. No. 6699) (“Reid Decl.”), Ex. 9, Figs. 24, 26, 27, 29.)

<sup>2</sup> “Dey SOF at ¶ \_\_” refers to the Statement of Undisputed Material Facts in Support of Dey, Inc. and Dey, L.P.’s Motion for Partial Summary Judgment, Dkt. No. 6695.

based on the existence of an OIG report that did not disclose specific differences for any particular drug manufactured by any particular defendant, but merely discussed differences between published prices and actual acquisition costs in generalized terms. In contrast, Dey's letters, which communicated directly with California that its AWP's did not reflect actual acquisition costs, told California enough.

Moreover, California ignores the fact that the issue of government knowledge is relevant to a defendant's *scienter* under the CFCA, that is whether the defendant knowingly presented or caused to be presented a false claim. *United States v. Shasta Servs. Inc.*, 440 F. Supp. 2d 1108, 1113 (E.D. Cal. 2006). California has never defined AWP as anything other than a price that appears in compendia, and has never offered any guidance as to how it should be defined. (Joint SOF at ¶ 20.<sup>3</sup>) In the absence of any guidance from California to the contrary, Dey's disclosures are more than sufficient to negate any showing that Dey "knowingly" caused the submission of false claims.

Finally, California makes its arguments concerning Dey's price notification letters in a vacuum, as though they were the only evidence that California had that published AWP's for generic drugs like Dey's did not accurately reflect providers' actual costs. In fact, the opposite is true. By 1999, California was well aware that compendia AWP's for generic drugs exceeded providers' actual acquisition costs by significant margins. (Joint SOF at ¶ 32.) Nonetheless, it continued to use compendia AWP with only modest discounts as one basis to calculate reimbursement for its own policy goals. (Joint SOF at ¶¶ 33, 35.)

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<sup>3</sup> "Joint SOF at ¶ \_\_\_" refers to the Defendants' Joint Statement of Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment, Dkt. No. 6703.

**B. Declining WACs**

California does not dispute that Dey reported WACs for its products to compendia that declined over time such that, by January 1999, a comparison of the published AWP to the published WAC would have revealed a “spread” in California’s parlance of at least 99 percent for each of the Dey Subject Drugs by January 1, 1999 and, for some drugs, spreads of more than 400 percent. (*See* Reid Decl., Ex. 9, Fig. 1.) Instead, California contends that Dey’s WACs were “irrelevant” to California, because California reimbursed based on AWP, rather than WAC. This argument misses the mark.

Dey expressly disclosed to California on multiple occasions that, unlike its AWP, which was set before launch and not subsequently changed, its WAC was its actual undiscounted invoice price to wholesalers.<sup>4</sup> (*See* Dey SOF at ¶ 35; Reid Decl., Exs. 29, 32, 34, 35.) Moreover, by reporting Dey’s WACs to compendia, Dey was making its actual invoice prices to wholesalers publicly available for anyone who wished to review it, including California. (*See* Joint SOF at ¶ 34.) The notion, therefore, that Dey could have knowingly caused the submission of false claims is simply untenable.

Moreover, the notion that WAC was “irrelevant” to California is not supported by the facts. As the record shows, California officials had considered using WAC as a reimbursement basis on multiple occasions in the late 1990s, and that, in 2004, Kevin Gorospe, Medi-Cal’s Pharmacy Policy Chief since 2000, had used WACs as a proxy for providers’ actual costs to assess a proposed change to reimbursement policy. (*See* Joint SOF at ¶¶ 33, 35, 54.) In short, even though California never actually used Dey’s WACs to calculate reimbursement, it

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<sup>4</sup> California’s contentions that Dey’s WACs did not reflect discounts and rebates and was higher than certain contract prices Dey negotiated with its customers does not change the fact that Dey’s WACs were its undiscounted invoice prices to wholesalers, as Dey began disclosing to California in 1999. (*See* Dey SOF at ¶ 17.)

nonetheless had access to them and understood that, unlike Dey's AWP, they represented an actual transaction price that was linked to market conditions.

**C. OIG Reports**

California does not dispute that publicly available reports prepared by the Office of Inspector General for the Department of Health and Human Services dating back to the mid-1990s documented large differences between compendia AWP and providers' actual acquisition costs for inhalation drugs such as albuterol sulfate and ipratropium bromide, two of the Dey Subject Drugs. Rather, California contends that these reports deal with Medicare and therefore would not necessarily have come within the purview of the Medi-Cal program. This argument is disingenuous. Setting aside Kevin Gorospe's testimony that Medi-Cal employees would have reviewed these types of reports (*see* Dey SOF at ¶ 27), these reports focus on Medicare reimbursement payments for these drugs, which, at the time, were based on AWP, just like Medi-Cal's reimbursement methodologies.

California's argument that Medi-Cal could not have "used" the information contained in these reports is therefore meritless. The reports are directly on point. Moreover, California itself controls Medi-Cal's pharmacy reimbursement methodology. California could have used the information in these reports to limit the reimbursement levels by, for instance, setting MACs, as other states have done.

**D. DOJ AWPs**

California does not dispute that, in 2000, it was aware of and had access to revised AWP for many of the Dey Subject Drugs, supplied by the United States Department of Justice and the National Association of Medicaid Fraud Control Units, that had been derived from market surveys of prices actually paid. Nor does California dispute that it chose not to use them, in part, because that they would impair access to care. Instead, California contends that

the DOJ AWP were “unworkable,” because they were “inaccurately low.” (*See* Cal. Dey Opp. Brief at 11.) In fact, the reasons California gives for not implementing the DOJ AWP simply confirm that California would not have used the AWP that it contends Dey should have reported.

To support its claim that the DOJ AWP were “inaccurately low”, California notes that the DOJ AWP “were based on surveys which included deeply discounted programs resulting in substantially lower prices, some decreased by as much as 80%.” (CA Resp. Dey SOF ¶ 39.<sup>5</sup>) While California contends that a discount of this magnitude is too large, and renders the DOJ AWP “unworkable,” Prof. Leitzinger’s “but for” prices reflect similar discounts.<sup>6</sup> California cannot have it both ways. If the DOJ AWP were too low, and it could not make use of them for this reason, then California’s damages analysis based on similar discounts should be rejected as well.

More essentially, California’s arguments concerning why it chose not to use the DOJ AWP misses the point. California had in its possession actual averages of market prices for many of Dey’s Subject Drugs that were substantially lower than the compendia AWP for those drugs and California chose not to use them at all for any purpose, not even to adjust Medi-Cal reimbursement it knew was well higher than acquisition cost. California did not adjust

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<sup>5</sup> “CA Resp. Dey SOF at ¶ \_\_\_” refers to the Plaintiffs’ Response to Defendants Dey, Inc. and Dey, L.P.’s Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Partial Summary Judgment and Statement of Additional Undisputed Facts in Opposition to Dey’s Motion for Partial Summary Judgment, Dkt. No. 6780.

<sup>6</sup> In California’s parlance, an 80 percent discount translates into a 400 percent “spread.” The “spreads” between the compendia AWP and the “but for” price California’s expert, Prof. Leitzinger, calculated for the Dey Subject Drugs are, in fact, in a similar range for many of the Subject Drugs for much of the relevant time period. (*See* Declaration of Nicholas N. Paul in Support of Plaintiffs’ Motion for Partial Summary Judgment as to Defendants Dey, L.P. and Dey, Inc., (Dkt. No. 6692) (“Paul Decl.”), Ex. 23, at Ex. A., Ex. 4.)



reimbursement downward precisely because, as the record reflects, they had policy goals and legal obligations that stood in the way of such a reduction.

### **III. THE SELF SERVING STATEMENTS BY MEDI-CAL OFFICIALS ARE NOT SUFFICIENT TO CREATE AN ISSUE OF FACT**

In a desperate attempt to stir up an issue of fact, California cites to snippets of deposition testimony by Dr. Kevin Gorospe and Stan Rosenstein concerning whether it was Medi-Cal's official policy to pay providers at rates that significantly exceeded their actual acquisition costs or to permit manufacturers to report AWP's that exceeded actual acquisition costs. These deposition snippets are not sufficient to create a question of fact on Dey's summary judgment motion.

First, they are inadmissible under the Federal Rules of Evidence, as they were elicited through leading questions asked by counsel for California during direct examination. *See* Fed. R. Evid. 611(c). Second, they are simply irrelevant to the questions before the court. In order for the government's knowledge to bar a claim, there is no requirement that Dey's practices must have comported to some official government policy in order for California's knowledge to preclude its CFCA claims. Rather, the relevant question is whether California knew of and acquiesced in Dey's conduct. *See Englund*, 2006 WL 3097941, at \*12. Given the extensive evidence in the record as of 1999, demonstrating California's knowledge of the differences between compendia AWP and providers' actual costs, for both the Dey Subject Drugs and for generic drugs in general, California's failure to ever articulate how AWP should be calculated and its continued reliance on AWP as a reimbursement benchmark is more than sufficient to defeat California's CFCA claims.

**IV. SUMMARY JUDGMENT SHOULD BE ENTERED IN DEY’S FAVOR FOR ALL THE DRUGS AT ISSUE FOR WHICH CALIFORNIA HAS NOT PURSUED ITS CLAIMS**

Dey has also moved for summary judgment on California’s claims arising from reimbursement payments for the Conceded Drugs. As Dey explained, there was no evidence in the record to support a showing of falsity under the CFCA for these drugs and no evidence that California had suffered damages as a result of reimbursement payments for these drugs, and California’s experts completely ignored them in their analyses. (*See* Dey Brief at 9-12.<sup>7</sup>) In its opposition, California does not dispute that there is no evidence of falsity in the record with regard to these drugs, concedes that it has not suffered damages for those drugs, and concedes that it has limited its claims to Dey’s acetylcysteine, albuterol, cromolyn, ipratropium bromide, and metaproterenol. (*See* Cal. Dey Opp. Brief at 11.) Accordingly, the court should enter judgment in Dey’s favor for any claims as to the Conceded Drugs.

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<sup>7</sup> “Dey Brief” refers to the Defendants Dey, Inc. and Dey, L.P.’s Brief in Support of Their Motion for Partial Summary Judgment, Dkt. No. 6709.

## **CONCLUSION**

For the reasons set forth herein, as well as the reasons set forth in Dey's Brief in Support of its Motion for Partial Summary Judgment, Dey respectfully requests that the Court grant this motion and enter judgment in favor of Dey on California's claims from January 1999 to the end of the relevant time period and enter judgment in favor of Dey on all of California's claims for all of California's claims arising from the NDCs not listed in paragraph 6 of Dey's Statement of Undisputed Material Facts.

Dated: January 15, 2010

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on January 15, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

\_\_\_\_\_  
/s/ Sarah L. Reid

Sarah L. Reid